**FOOD AND DRUG ADMINISTRATION**
Center for Drug Evaluation and Research

***Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)***
Hilton Hotel, Washington DC/Silver Spring, Maryland
July 19, 2011

# DRAFT AGENDA

*The committee will discuss new drug application (NDA) 202293 dapagliflozin, manufactured by Bristol-Myers Squibb and AstraZeneca. Dapagliflozin is the first drug in the class of sodium-glucose co-transporter 2 (SGLT2) inhibitors, developed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus*

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| 8:00 a.m. | Call to Order and Introduction of Committee | **TBA**<br>Acting Chair, EMDAC |
| 8:05 a.m. | Conflict of Interest Statement | **Paul T. Tran, R.Ph**<br>Designated Federal Officer, EMDAC |
| 8:15 a.m. | Introduction/Background | **FDA** |
| 8:30 a.m. | **SPONSOR PRESENTATION** | **Bristol-Myers Squibb/AstraZeneca** |
| | Introduction | |
| | Medical Need for New Anti-Diabetic Treatments | |
| | Dapagliflozin: Overview of Mode of Action and Introduction to Development Program | |
| | Clinical Efficacy | |
| | Safety | |
| | Overall Benefit –Risk | |
| | Dapagliflozin Post-Approval | |
| 10:00 a.m. | Clarifying Questions from the Committee | |
| 10:15 a.m. | **BREAK** | |
| 10:30 a.m. | **FDA PRESENTATION** | |
| | Overview of Efficacy | |
| | Safety Issues | |
| 12:00 p.m. | Clarifying Questions from the Committee | |
| 12:15 p.m. | **LUNCH** | |

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## DRAFT AGENDA (cont.)

1:15 p.m. Open Public Hearing Session

2:15 p.m. Questions to the Committee/Committee Discussion

2:45 p.m. **BREAK**

3:00 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**